



## ENZYMATIC THERAPY INCORPORATED

*What **Better** feels like.™*

**INTEGRATIVE THERAPEUTICS INC.™**  
NF Formulas ♦ PhytoPharmica  
Tyler Encapsulations ♦ Vitaline Formulas

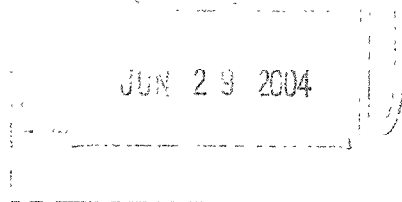
9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 ♦ F: 503.582.0467

**ENZYMATIC THERAPY™  
&  
PHYTOPHARMICA™**

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 ♦ F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 ♦ F: 920.469.4418 (Phyto)

June 16, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740



RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
ViraPlex™ EB	ViraPlex™ EB provides the nutrient building blocks necessary for optimal immune system function in adults, while Esberitox® stimulates the immune system into action.*	Vitamin A (as acetate), Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin B12 (as cyanocobalamin), Pantothenic Acid (as calcium D-pantothenate), Calcium (as calcium lactate), Magnesium (as magnesium citrate), Zinc (as zinc gluconate), European Elder (Sambucus nigra) Berry Extract, Alfalfa (Medicago sativa) Aerial Part Extract, Astragalus (Astragalus membranaceus) Root Extract, Mixed Bioflavonoids (from citrus fruits)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

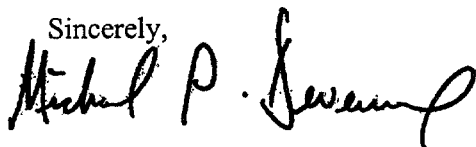
Date: 6/16/04

97S 0162

LET 14194

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" being the most prominent.

Michael P. Devereux  
Chief Financial Officer



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
ViraPlex™ EB	When you need a one-two punch of immune protection use ViraPlex™ EB and Esberitox®!*	Vitamin A (as acetate), Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin B12 (as cyanocobalamin), Pantothenic Acid (as calcium D-pantothenate), Calcium (as calcium lactate), Magnesium (as magnesium citrate), Zinc (as zinc gluconate), European Elder (Sambucus nigra) Berry Extract, Alfalfa (Medicago sativa) Aerial Part Extract, Astragalus (Astragalus membranaceus) Root Extract, Mixed Bioflavonoids (from citrus fruits)

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Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 6/16/04

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Sincerely,  


Michael P. Devereux  
Chief Financial Officer